



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Martis et al.  
Appl. No.: 09/955,248  
Conf. No.: 8992  
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Title: BIOCHEMICALLY BALANCED PERITONEAL DIALYSIS SOLUTIONS  
Art Unit: 1621  
Examiner: R. Keys  
Docket No.: DI-4641 CONT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

### **AFFIDAVIT OF LEO MARTIS, PH.D**

I, Leo Martis, Ph.D., hereby state as follows:

1. I am a co-inventor of the above-referenced U.S. Patent Application No. 09/955,248 entitled "BIOCHEMICALLY BALANCED PERITONEAL DIALYSIS SOLUTIONS." I earned a Ph.D. in pharmacology in 1973, a M.S. in pharmaceutical chemistry in 1970, and a B.S. in Chemistry in 1965. I have been a research chemist at Baxter International Inc. since 1974 and have been a research scientist working in the field of peritoneal dialysis solutions since 1978.

2. I have reviewed Schambye et al., THE CYTOTOXICITY OF CONTINUOUS AMBULATORY PERITONEAL DIALYSIS SOLUTIONS WITH DIFFERENT BICARBONATE/LACTATE RATIOS, Peritoneal Dialysis International, Vol. 13, Supplement 2, S116-S118. I have calculated the carbon dioxide partial pressure for solution 91c in Table 1 of this reference based on the Henderson-Hasselbalch Equation and provide below the detailed results of this calculation.

3. The formulation for solution 91c is as follows:

Pyruvate	2.5 mM
Lactate	12.5 mM
Bicarbonate	20.0 mM
pH	7.0

4. The carbon dioxide partial pressure ( $pCO_2$ ) for solution 91c was calculated at 86.6 mmHg as follows:

$$\text{I) } pCO_2 = 29.6 \text{ atm/(mol/L)} \times \text{concentration CO}_2$$

$$\text{II) concentration CO}_2 = 20\text{mM} \times 19.22\% \times 99.7\% = 3.83 \text{ mM} = 0.00383 \text{ mol/L}$$

where 19.22% is the amount of total bicarbonate which is  $H_2CO_3$  at pH 7; and

where 99.7% is the amount of  $H_2CO_3$  which is actually  $CO_2$

$$\text{III) } pCO_2 = 29.6 \text{ atm/(mol/L)} \times 0.00383 \text{ mol/L} = 0.114 \text{ atm}$$

$$\text{IV) } pCO_2 = 0.114 \text{ atm} \times (760\text{mmHg}/1 \text{ atm}) = 86.6 \text{ mmHg}$$

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: May 18, 2005



Leo Martis, Ph.D.